It is believed that claims 1-7 and 9-18 recite a patentable improvement in the art. Favorable action is solicited.

Respectfully submitted,

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31KIRCHHOLTES PRE-AMENDMENT

Version with Markings to Show Changes Made

IN THE CLAIMS:

1. [A high purity composition comprising] Highly pure (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one, [characterized in that the said composition comprises] comprising (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount less than 0.5% by weight.

2. The [composition] highly pure (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one according to claim 1 [characterized in that], wherein the amount of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one is 0.25% or less.

3. The [composition] highly pure (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one according to claim 1 [characterized in that], wherein the amount of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one is 0.1% or less.

4. A process for preparing the [high purity compositions of claims 1-3 characterized in that] highly pure (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one of claim 1, comprising aging crystals of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one [are allowed to age] in the presence of water for at least 24 hours.

6. The process according to [claims 4 or 5 characterized in that] claim 4, wherein the crystals are formed in the last step of [the Tibolone] synthesis comprising the steps of
a. reacting (7α,17α)-3,3-dimethoxy-17-hydroxy-7-methyl-19-norpregn-5(10)-en-20-yn-3-one in an organic solvent with a weak acidic aqueous solution,
b. pouring out the solution in water which is [made] slightly alkaline, and
c. washing the crystals with water which is [made] slightly alkaline.

7. A pharmaceutical dosage unit [obtainable by admixture of] comprising a pharmaceutically suitable solid carrier and the [composition according to any one of the claims 1-3] highly pure (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one of claim 1.

9. A dosage unit comprising a pharmaceutically suitable solid carrier and (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one in an amount of less than 2.50 mg, [and having a shelf life specification comprising] which is less than 5% by weight of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one.

10. The dosage unit according to claim 9, wherein [characterized in that] (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one is present in an amount of 1.25 mg or less.

11. The dosage unit according to claim 9 [characterized in that], wherein (7α,17α)-17-hydroxy-7-methyl-19-nor-17-

pregn-5(10)-en-20-yn-3-one is present in an amount of 0.625 mg or less.

12. The dosage unit according to [claims 9-11] claim 9, wherein the shelf life is at least 1.5 [, more preferably 2] years.

13. The dosage unit according to [claim 9-11] claim 9, wherein at a shelf life period of 6 months the amount of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one is 3% or less[, more preferably 2% or less] by weight of the (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one.

14. The dosage unit according to claim 13 wherein the shelf life period is 1[,preferably 1½ year, more preferably 2 years] year.